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HIGHLY CONFIDENTIAL – FILED UNDER SEAL

January 27, 2016

Honorable Alison J. Nathan
United States District Judge
Thurgood Marshall United States Courthouse
40 Foley Square, Room 906
New York, New York 10007

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Re: *Braintree Laboratories, Inc. v. Breckenridge Pharmaceutical, Inc.*
Case No.: 12-cv-6851-AJN

Dear Judge Nathan:

We represent Defendant Breckenridge Pharmaceutical, Inc. (“Breckenridge”) in this action. In accordance with the schedule in this Court’s Order dated June 23, 2015 (D.I. 80), Breckenridge filed a Motion for Summary Judgment of Noninfringement on July 6, 2015 (D.I. 84-87) (“Breckenridge’s Motion”).¹ The motion was fully briefed as of July 27, 2015. As required by Your Honor’s Individual Rule 3.H., on September 30, 2015, Breckenridge filed a letter to alert the Court that it had been sixty days since its motion for summary judgment was fully briefed. (D.I. 101).

Breckenridge respectfully requests that the Court schedule oral argument or decide Breckenridge’s Motion as soon as possible. [REDACTED]

REDACTED

1 Breckenridge’s Motion was originally filed on July 15, 2013, and briefing was completed on August 13, 2013. (See D.I. 42-56.) After the original briefing, the case was temporarily placed on administrative hold pending the outcome of a Federal Circuit appeal in the first ANDA filer’s case, *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, 749 F.3d 1349 (Fed. Cir. 2014). On this Court’s order, Breckenridge refiled its motion for summary judgment on July 6, 2015 with briefing updated “to account for developments in the Novel action as well as any developments in the law.” (See D.I. 80.)



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Honorable Allison J. Nathan
Page 2

January 27, 2016

REDACTED

[REDACTED]

In June of last year, this Court recognized that further delays in deciding Breckenridge's Motion were not warranted, and agreed to proceed to a decision. (D.I. 80.) That remains the correct decision.² Breckenridge respectfully requests that the Court take action on Breckenridge's Motion so that Breckenridge can move forward toward providing the public with a generic product.

We appreciate the Court's consideration.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read 'Steven Lieberman'.

Steven Lieberman

cc: All counsel of record

² As this Court is aware, briefing for the pending appeal in *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, No. 15-1700 (Fed. Cir.) was completed just this week, with oral argument likely to be scheduled several months later. (See D.I. 24 in *Braintree Labs., Inc. v. Taro Pharms. USA, Inc.*, CA No. 14-cv-8147-AJN). Briefing in the appeal was delayed by a total of about four months as a result of various requests by both appellant and appellee. See Ex. B (Docket in Fed. Cir. No. 15-1700). A decision from the Federal Circuit in the *Novel* case is not expected for at least several months, and in any event does not involve any of the same issues presented by Breckenridge's Motion. (See D.I. 75 at 3.)

EXHIBIT A

**(January 27, 2016 Letter from Steven Lieberman to Judge Nathan –
Second Declaration of JoAnna L. Walsh)**

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BRAINTREE LABORATORIES, INC.,

Plaintiff,

v.

BRECKENRIDGE
PHARMACEUTICAL, INC.,

Defendant.

Civil Action No. 12-cv-6851-AJN
ECF Case

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SECOND DECLARATION OF JOANNA L. WALSH

I, JoAnna L. Walsh, declare:

I have personal knowledge of the facts stated in this declaration. If called upon to do so, I could, and would, competently testify on the matters set forth herein.

1. I am the same JoAnna L. Walsh that submitted the Declaration of JoAnna L. Walsh in this action on June 16, 2015, on behalf of Defendant Breckenridge Pharmaceutical, Inc. ("Breckenridge").

2. I hereby incorporate by reference my background and experience provided in the earlier declaration as it is essentially the same; however, my current position is Senior Manager, Regulatory Affairs of Breckenridge, where I have been employed since January, 2010.

3. I make this declaration based upon my own knowledge and experience and upon the documents and information to which I have access in the course of my employment with Breckenridge.

4. Since September 2013, I have been the primary project manager responsible for ANDA No. 204135 filed with the Food and Drug Administration ("FDA") ("Breckenridge's ANDA").

5. As I provided in my earlier declaration, [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] REDACTED

6. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] REDACTED

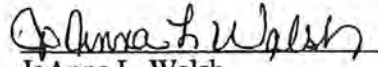
7. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] REDACTED

8. [REDACTED]

[REDACTED]
[REDACTED]

I declare under penalty of perjury that the foregoing is true and correct.
Executed on January 26, 2016.

A handwritten signature in black ink, appearing to read "JoAnna L. Walsh", written over a horizontal line.

JoAnna L. Walsh
Senior Manager, Regulatory Affairs
Breckenridge Pharmaceutical, Inc.

EXHIBIT B

**(January 27, 2016 Letter from Steven Lieberman to Judge Nathan –
PACER docket for *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*,
Appeal No. 2015-1700 (Fed. Cir.))**

General Docket
United States Court of Appeals for the Federal Circuit

Court of Appeals Docket #: 15-1700 Nature of Suit: 830 Patent Infringement (Fed. Question) Braintree Laboratories, Inc. v. Novel Laboratories, Inc. Appeal From: United States District Court for the District of New Jersey Fee Status: fee paid	Docketed: 06/04/2015
Case Type Information: 1) Civil Private 2) - 3) -	
Originating Court Information: District: 0312-3 : <u>3:11-cv-01341-PGS-LHG</u> Trial Judge: Peter G. Sheridan, United States District Judge Date Filed: 03/09/2011 Date NOA Filed: 06/02/2015 Date Rec'd COA: 06/04/2015	
Prior Cases: <u>13-1438</u> Date Filed: 06/10/2013 Date Disposed: 04/22/2014 Disposition: Affirmed-in-part, Reversed-in-part, Rmd	
Current Cases: None	

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 Plaintiff - Appellee

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v.

NOVEL LABORATORIES, INC.
Defendant - Appellant

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BRAINTREE LABORATORIES, INC.,

Plaintiff - Appellee


v.

NOVEL LABORATORIES, INC.,

Defendant - Appellant

06/04/2015	<input type="checkbox"/> <u>1</u> 92 pg, 774.4 KB	Appeal docketed. Received: 06/04/2015. [245920] Entry of Appearance due 06/18/2015. Certificate of Interest is due on 06/18/2015. Docketing Statement due 06/18/2015. Appellant's brief is due 08/03/2015.
06/18/2015	<input type="checkbox"/> <u>2</u> 2 pg, 571.11 KB	Entry of appearance for H. Keeto Sabharwal as principal counsel for Appellant Novel Laboratories, Inc.. Service: 06/18/2015 by email. [249623]
06/18/2015	<input type="checkbox"/> <u>3</u> 2 pg, 571.33 KB	Entry of appearance for Byron L. Pickard as of counsel for Appellant Novel Laboratories, Inc.. Service: 06/18/2015 by email. [249625]
06/18/2015	<input type="checkbox"/> <u>4</u> 2 pg, 570.91 KB	Entry of appearance for Nirav N. Desai as of counsel for Appellant Novel Laboratories, Inc.. Service: 06/18/2015 by email. [249627]
06/18/2015	<input type="checkbox"/> <u>5</u> 1 pg, 1.49 MB	Entry of appearance for Ronald J. Schutz as of counsel for Appellant Novel Laboratories, Inc.. Service: 06/18/2015 by email. [249664]
06/18/2015	<input type="checkbox"/> <u>6</u>	Entry of appearance for Oren D. Langer as of counsel for Appellant Novel Laboratories, Inc.. Service: 06/18/2015 by email. [249668]
06/18/2015	<input type="checkbox"/> <u>7</u> 2 pg, 531.4 KB	Entry of appearance for Matthew B. McFarlane as of counsel for Appellant Novel Laboratories, Inc.. Service: 06/18/2015 by email. [249669]
06/18/2015	<input type="checkbox"/> <u>8</u> 3 pg, 516.17 KB	Certificate of Interest for the Appellant Novel Laboratories, Inc.. Service: 06/18/2015 by email. [249670]
06/18/2015	<input type="checkbox"/> <u>9</u> 5 pg, 534.97 KB	Docketing Statement for the Appellant Novel Laboratories, Inc.. Service: 06/18/2015 by email. [249671]
06/18/2015	<input type="checkbox"/> <u>10</u>	Corrected Entry of appearance for Ronald J. Schutz as of counsel for Appellant Novel Laboratories, Inc.. Service: 06/18/2015 by email. [249675]
06/18/2015	<input type="checkbox"/> <u>11</u> 1 pg, 49.46 KB	Entry of appearance for John J. Regan as principal counsel for Appellee Braintree Laboratories, Inc.. Service: 06/18/2015 by email. [249722]
06/18/2015	<input type="checkbox"/> <u>12</u> 1 pg, 49.91 KB	Entry of appearance for Christopher R. Noyes as of counsel for Appellee Braintree Laboratories, Inc.. Service: 06/18/2015 by email. [249726]
06/18/2015	<input type="checkbox"/> <u>13</u> 1 pg, 49.49 KB	Entry of appearance for Mark C. Fleming as of counsel for Appellee Braintree Laboratories, Inc.. Service: 06/18/2015 by email. [249727]
06/18/2015	<input type="checkbox"/> <u>14</u> 1 pg, 49.71 KB	Entry of appearance for Anna E. Lumelsky as of counsel for Appellee Braintree Laboratories, Inc.. Service: 06/18/2015 by email. [249728]
06/18/2015	<input type="checkbox"/> <u>15</u> 1 pg, 50.49 KB	Entry of appearance for Michael A. Greene as of counsel for Appellee Braintree Laboratories, Inc.. Service: 06/18/2015 by email. [249730]
06/18/2015	<input type="checkbox"/> <u>16</u> 1 pg, 49.53 KB	Certificate of Interest for the Appellee Braintree Laboratories, Inc.. Service: 06/18/2015 by email. [249732]
06/18/2015	<input type="checkbox"/> <u>17</u> 5 pg, 51.7 KB	Docketing Statement for the Appellee Braintree Laboratories, Inc.. Service: 06/18/2015 by email. [249733]
06/18/2015	<input type="checkbox"/> <u>18</u>	Entry of appearance for Ronald M. Daignault as of counsel for Appellant Novel Laboratories, Inc.. Service: 06/18/2015 by email. [249766]
06/19/2015	<input type="checkbox"/> <u>19</u>	NOTICE OF DEFICIENCY: The attorney entries of appearance for OREN LANGER, RONALD DAIGNAULT, RONALD SCHUTZ Document Nos. [6] [10] [18] filed by Appellant Novel Laboratories, Inc. in 15-1700 are not text searchable and therefore cannot be accepted for filing at this time. You are being afforded the opportunity to correct the deficiency. At the discretion of the court, the corrected document may be accepted for filing if received before midnight (EST) on the date of this notice. [249823]
06/19/2015	<input type="checkbox"/> <u>20</u> 2 pg, 675.86 KB	Corrected Entry of appearance for Ronald M. Daignault as of counsel for Appellant Novel Laboratories, Inc.. Service: 06/19/2015 by email. [249863]
06/19/2015	<input type="checkbox"/> <u>21</u>	CLERK'S OFFICE QUALITY CONTROL MESSAGE: re:attorney entry of appearance [RONALD DAIGNAULT] Docket No. [20]. ERROR: Appellant's counsel RONALD DAIGNAULT's entry of appearance reflects a different law firm affiliation than his registered ECF filer account. Mr. Daignault's current law firm affiliation in ECF is Robins Kaplan Miller & Ciresi LLP. CORRECTION: Counsel DAIGNAULT should update his ECF account ASAP with his current firm affiliation & contact information. Go to www.pacer.gov "manage my appellate filer account". THIS MESSAGE IS FOR INFORMATIONAL PURPOSES ONLY. [249907]
06/19/2015	<input type="checkbox"/> <u>22</u> 2 pg, 529.91 KB	Corrected Entry of appearance for Oren D. Langer as of counsel for Appellant Novel Laboratories, Inc.. Service: 06/19/2015 by email. [250033]
06/19/2015	<input type="checkbox"/> <u>23</u> 2 pg, 529.07 KB	Corrected Entry of appearance for Ronald J. Schutz as of counsel for Appellant Novel Laboratories, Inc.. Service: 06/19/2015 by email. [250037]

06/19/2015	<input type="checkbox"/> <u>24</u> 23 pg, 530.43 KB	Notice from Appellee Braintree Laboratories, Inc. regarding postjudgment motions. Service: 06/19/2015 by email. [250135]
06/22/2015	<input type="checkbox"/> <u>25</u> 2 pg, 66.71 KB	ORDER deactivating appeal. Service as of this date by Clerk of Court. [250223]
06/25/2015	<input type="checkbox"/> <u>26</u> 6 pg, 158.33 KB	Notice from Appellee Braintree Laboratories, Inc. regarding postjudgment motions. Service: 06/25/2015 by email. [251620]
06/29/2015	<input type="checkbox"/> <u>27</u> 2 pg, 66.88 KB	ORDER reactivating case. Appellant's brief is due on August 10, 2015. Service as of this date by Clerk of Court. [252132]
07/17/2015	<input type="checkbox"/> <u>28</u> 4 pg, 23.98 KB	Certificate of Compliance with Fed. Cir. R. 11(d) (Trial Court) for Appellee Braintree Laboratories, Inc.. Service: 07/17/2015 by email. [257382]
07/20/2015	<input type="checkbox"/> <u>29</u> 3 pg, 74.7 KB	Certificate of Compliance with Fed. Cir. R. 11(d) (Trial Court) for Appellant Novel Laboratories, Inc.. Service: 07/20/2015 by email. [257578]
07/30/2015	<input type="checkbox"/> <u>30</u> 9 pg, 55.76 KB	MOTION of Appellant Novel Laboratories, Inc. to extend the time to 09/09/2015 at 11:59 pm to file the appellant/petitioner's principal brief. Response/Opposition is due 08/13/2015 [Consent: unopposed]. Service: 07/30/2015 by email. [260875]
07/31/2015	<input type="checkbox"/> <u>31</u> 2 pg, 66.93 KB	ORDER granting motion to extend time to file appellant's principal brief [30] filed by Appellant Novel Laboratories, Inc. Brief due 09/09/2015. Service as of this date by Clerk of Court. [261062]
09/09/2015	<input type="checkbox"/> <u>32</u> 98 pg, 4.92 MB	TENDERED from Appellant Novel Laboratories, Inc.. Title: OPENING BRIEF. Service: 09/09/2015 by email. [270795]
09/09/2015	<input type="checkbox"/> <u>33</u> 88 pg, 4.9 MB	BRIEF FILED for Appellant Novel Laboratories, Inc. [32]. Number of Pages: 47. Service: 09/09/2015 by email. Pursuant to ECF-10, filer is directed to file six copies of the brief in paper format. The paper copies of the brief should be received by the court on or before 09/16/2015. Appellee Braintree Laboratories, Inc. brief is due 10/22/2015. [271284]
09/14/2015	<input type="checkbox"/> <u>34</u>	6 paper copies of the Opening Brief [33] received from Appellant Novel Laboratories, Inc.. [271997]
10/05/2015	<input type="checkbox"/> <u>35</u> 9 pg, 50.76 KB	MOTION of Appellee Braintree Laboratories, Inc. to extend the time to 11/23/2015 at 11:59 pm to file the appellee/respondent/cross-appellant's principal brief. Response/Opposition is due 10/19/2015 [Consent: unopposed]. Service: 10/05/2015 by email. [277638]
10/06/2015	<input type="checkbox"/> <u>36</u>	**TEXT ONLY** ORDER granting motion to extend time to file appellee/respondent/cross-appellant principal brief [35] filed by Appellee Braintree Laboratories, Inc. Appellee Braintree Laboratories, Inc. brief due 11/23/2015. Service as of this date by Clerk of Court. This order has been issued without an attached document and is official and binding. [278180]
11/23/2015	<input type="checkbox"/> <u>37</u> 77 pg, 2.28 MB	TENDERED from Appellee Braintree Laboratories, Inc.. Title: OPENING BRIEF. Service: 11/23/2015 by email. [291241]
11/23/2015	<input type="checkbox"/> <u>38</u> 77 pg, 2.2 MB	BRIEF FILED for Appellee Braintree Laboratories, Inc. [37]. Number of Pages: 68. Service: 11/23/2015 by email. Pursuant to ECF-10, filer is directed to file six copies of the brief in paper format. The paper copies of the brief should be received by the court on or before 11/30/2015. Appellant Novel Laboratories, Inc. reply brief is due 12/10/2015. [291289]
11/24/2015	<input type="checkbox"/> <u>39</u> 2 pg, 96.69 KB	Entry of appearance for William A. Rakoczy as of counsel for Appellant Novel Laboratories, Inc.. Service: 11/24/2015 by email. [291683]
11/24/2015	<input type="checkbox"/> <u>40</u> 2 pg, 114.54 KB	Entry of appearance for Paul J. Molino as of counsel for Appellant Novel Laboratories, Inc.. Service: 11/24/2015 by email. [291684]
11/24/2015	<input type="checkbox"/> <u>41</u> 2 pg, 113.63 KB	Entry of appearance for Deanne M. Mazzochi as of counsel for Appellant Novel Laboratories, Inc.. Service: 11/24/2015 by email. [291686]
11/24/2015	<input type="checkbox"/> <u>42</u> 2 pg, 114.08 KB	Entry of appearance for Peter J. Curtin as of counsel for Appellant Novel Laboratories, Inc.. Service: 11/24/2015 by email. [291688]
11/24/2015	<input type="checkbox"/> <u>43</u> 2 pg, 111.35 KB	Entry of appearance for Patrick C. Kilgore as of counsel for Appellant Novel Laboratories, Inc.. Service: 11/24/2015 by email. [291689]
11/24/2015	<input type="checkbox"/> <u>44</u> 2 pg, 85.74 KB	Amended Certificate of Interest for the Appellant Novel Laboratories, Inc.. Service: 11/24/2015 by email. [291690]
11/24/2015	<input type="checkbox"/> <u>45</u> 4 pg, 30.71 KB	MOTION of Appellant Novel Laboratories, Inc. to substitute attorney. Response/Opposition is due 12/07/2015 [Consent: unopposed]. Service: 11/24/2015 by email. [291692]
11/24/2015	<input type="checkbox"/> <u>46</u> 6 pg, 37.91 KB	MOTION of Appellant Novel Laboratories, Inc. to extend the time to 01/25/2016 to file the reply brief. Response/Opposition is due 12/07/2015 [Consent: unopposed]. Service: 11/24/2015 by email. [291694]
11/25/2015	<input type="checkbox"/> <u>47</u>	**TEXT ONLY** ORDER granting motion to substitute attorney [45] filed by Appellant Novel Laboratories, Inc. Service as of this date by Clerk of Court. This order has been issued without an attached document and is official and binding. [291772]

11/25/2015	<input type="checkbox"/> <u>48</u> 2 pg, 177.22 KB	Amended Entry of appearance for William A. Rakoczy as principal counsel for Appellant Novel Laboratories, Inc.. Service: 11/25/2015 by email. [291805]
11/25/2015	<input type="checkbox"/> <u>49</u>	6 paper copies of the Opening Response Brief <u>[38]</u> received from Appellee Braintree Laboratories, Inc.. [291896]
11/25/2015	<input type="checkbox"/> <u>50</u>	**TEXT ONLY** ORDER granting motion to extend time to file reply brief <u>[46]</u> filed by Appellant Novel Laboratories, Inc. Reply brief is due 01/25/2016. Service as of this date by Clerk of Court. This order has been issued without an attached document and is official and binding. [291957]
01/26/2016	<input type="checkbox"/> <u>51</u>  0 pg, 0 KB	TENDERED from Appellant Novel Laboratories, Inc.. Title: REPLY BRIEF. Service: 01/25/2016 by email. [305645]

15-1700 Docket

Page 8 of 8

☒ Documents and Docket Summary☐ Documents Only☒ Include Page NumbersSelected Pages: Selected Size:

Totals reflect accessible documents only and do not include unauthorized restricted documents.

PACER Service Center			
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01/26/2016 15:56:43			
PACER Login:	Rothwell:2621850:0	Client Code:	3421-110
Description:	Docket Report (filtered)	Search Criteria:	15-1700
Billable Pages:	4	Cost:	0.40

CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2016, a true and correct copy of the foregoing **JANUARY 27, 2016 LETTER FROM STEVEN LIEBERMAN TO JUDGE NATHAN** was filed through the Court's Electronic Filing System (ECF), and was served electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Erik van Leeuwen
Erik van Leeuwen
Litigation Operations Manager
Rothwell, Figg, Ernst & Manbeck, P.C.